Section 5: 510(k) Summary

Submitter Name:	Volcano Corporation
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Date Prepared:	August 14, 2009
Device Trade Name:	**Eagle Eye® Platinum Digital IVUS Catheter**
Device Common Name:	Intravascular IVUS Imaging Catheter
Classification Name:	Diagnostic Intravascular Catheter, 870.1200 Diagnostic Ultrasound Transducer, 892.1570
Classification Code:	OBJ: Catheter, Ultrasound, Intravascular ITX: Transducer, Ultrasonic, Diagnostic
Predicate Device:	Eagle Eye® Gold IVUS Imaging Catheter, 510(k) Number K073473, Classification Code: OBJ, Regulation Number 870.1200

DEC 10 2009

Device Description:

Eagle Eye® Platinum Digital IVUS Catheters incorporate a cylindrical ultrasound transducer array used to radiate acoustic energy into the surrounding tissue and detects the subsequent ultrasonic echoes. The information from the echoes is used to generate real-time images of the coronary and peripheral vessels.

The Eagle Eye® Platinum catheter utilizes an internal lumen that allows the catheter to track over the 0.014" (0.36 mm) guide wire. The guide wire exits from the guide wire lumen approximately 24 cm proximal to the catheter tip. The Eagle Eye® Platinum catheter is introduced percutaneously or via surgical cut down into the vascular system.

Two types of markers are used along the shaft length:

1. Three radio-opaque markers applied along the length of the distal inner-shaft to aide in positioning the catheter in the vascular anatomy during an angiographic procedure.

2. A pair of brachial and femoral (one each) shaft markers located on the outer proximal shaft aid in gauging the IVUS transducer position relative to the guiding catheter tip when introducing the EEP catheter through the guiding catheter.

A hub fitting is attached to the proximal end of the catheter via an integrated strain relief and provides a channel for the ultrasound scanner leads to interface electrically with the patient interface module (PIM) connector of the imaging system.

~~The Eagle Eye® Platinum catheters may only be used with the Volcano In-Vision Imaging System, Volcano s5, or~~ Volcano s5i Imaging Systems. The catheters are designed to work with Volcano VH IVUS system software v 1.2 or higher. This catheter will not operate if connected to any other imaging system.

Intended Use: Eagle Eye® Platinum Digital IVUS catheters are designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in cerebral vessels. The Eagle Eye® Platinum Digital IVUS catheters are designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

Intended Users: Eagle Eye® Platinum Digital IVUS catheters are designed and intended for single use by interventional cardiologists and cardiac catheterization lab staff.

Device Design Requirements: Biocompatibility, shelf life, sterilization, package integrity, and design verification testing will be performed to prove that the materials and manufacturing processes selected for the catheter body of the Eagle Eye® Platinum catheter do not pose a significant safety risk to the patient.

Substantial Equivalence Discussion: The Eagle Eye® Platinum Digital IVUS Catheter uses the same fundamental scientific technologies and has the same intended use as that of the predicate device, the Eagle Eye® Gold IVUS Imaging Catheter. The Eagle Eye® Platinum catheter is a redesign of the catheter body elements of the Eagle Eye® Gold only and does not change the ultrasound signal or signal processing used for the predicate device. The ultrasound scanner of the Eagle Eye® Platinum is identical to that of the Eagle Eye® Gold however the blood contacting materials not included in the ultrasound scanner and the catheter body manufacturing processes have been changed and updated to represent current state of the art materials and methods.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Volcano Corporation
C/O Donovan May, Regulatory Affairs Engineer
2870 Kilgore Rd.
Rancho Cordova, CA 95670

DEC 10 2009

Re: K092596
Trade/Device Name: Eagle Eye Platinum Digital IVUS Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ, ITX
Dated: November 11, 2009
Received: November 13, 2009

Dear Mr. May:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use

510(k) Number (if known): K092596

Device Name: **Eagle Eye® Platinum Digital IVUS Catheter**

Indications for Use: Eagle Eye® Platinum Digital IVUS catheters are designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in cerebral vessels. The Eagle Eye® Platinum Digital IVUS catheters are designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

Prescription Use **YES** (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use **NO** (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092596